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Tokuhiro Chano

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KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER

REDDIG, PETER J

ART UNIT

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1642

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/516,558

Applicant(s)

CHANO ET AL.

Examiner

Peter J. Reddig

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-3 and 17, drawn to a protein or polypeptide which is present in nucleus of human or animal cell and which has a transcription factor function and/or a function that can induce expression of retinoblastoma gene (RB1 gene) or a gene product thereof and a pharmaceutical composition for use in treatment of multidrug resistance that is resistance to treatment with anticancer agents, wherein the pharmaceutical composition comprises the polypeptide or protein according to claim 1.

Group 2, claim(s) 4-10 and 17, drawn to a nucleic acid coding for the polypeptide or protein according to claim 1, or a complementary strand thereof and a pharmaceutical composition for use in treatment of multidrug resistance that is resistance to treatment with anticancer agents, wherein the pharmaceutical composition comprises a nucleic acid coding for the the polypeptide or protein according to claim 1 or a complementary strand thereof, a recombinant vector containing the nucleic acid, and a transformant that was transformed with the recombinant vector.

Group 3, claim(s) 11 and 17, drawn to an antibody that immunologically recognizes the polypeptide or protein according to claim 1 and a pharmaceutical composition for use in treatment of multidrug resistance that is resistance to treatment with anticancer agents, wherein the pharmaceutical composition comprises an antibody that immunologically recognizes the polypeptide or protein.

Group 4, claim(s) 12, drawn to a method of screening for compounds that inhibit or enhance a function that can **induce transcription factor activity** of the RB1 gene of the polypeptide or protein according to claim 1, wherein the method utilizes the polypeptide or the protein.

Group 5, claim(s) 12, drawn to a method of screening for compounds that inhibit or enhance a function that can **induce expression** of the RB1 gene of the polypeptide or protein according to claim 1, wherein the method utilizes the **polypeptide or the protein**.

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Group 6, claim(s) 12, drawn to a method of screening for compounds that inhibit or enhance a function that can induce **transcription factor activity and expression** of the RB1 gene of the polypeptide or protein according to claim 1, wherein the method utilizes the **polypeptide or the protein**.

Group 7, claim(s) 12, drawn to a method of screening for compounds that inhibit or enhance a function that can induce **transcription factor activity** of the RB1 gene of the polypeptide or protein according to claim 1, wherein the method utilizes an **antibody that immunologically recognizes the polypeptide or protein**.

Group 8, claim(s) 12, drawn to a method of screening for compounds that inhibit or enhance a function that can **induce expression** of the RB1 gene of the polypeptide or protein according to claim 1, wherein the method utilizes an antibody **that immunologically recognizes the polypeptide or protein**.

Group 9, claim(s) 12, drawn to a method of screening for compounds that inhibit or enhance a function that can induce **transcription factor activity and expression** of RB1 gene of the polypeptide or protein according to claim 1, wherein the method utilizes **an antibody that immunologically recognizes the polypeptide or protein**.

Group 10, claim(s) 13, drawn to a method of screening for compounds that interact with the nucleic acid according to claim 4 to inhibit or enhance expression of the nucleic acid, wherein the method utilizes the nucleic acid, a recombinant vector containing the nucleic acid a transformant that was transformed with the recombinant vector, or nucleic acid primers set forth in SEQ ID NOS: 5 to 132 in the sequence listing which hybridize under stringent conditions with the nucleic acid.

Group 11, claim(s) 14 and 15, drawn to a compound that was screened by the screening method according to claim 12, **using the protein or polypeptide of claim 1**, that can induce **transcription factor activity and expression** of the RB1 gene of the polypeptide or protein according to claim 1.

Group 12, claim(s) 14 and 15, drawn to a compound that was screened by the screening method according to claim 12, **using the protein or polypeptide of claim 1**, that can induce **transcription factor activity** of the RB1 gene of the polypeptide or protein according to claim 1.

Group 13, claim(s) 14 and 15, drawn to a compound that was screened by the screening method according to claim 12, **using the protein or polypeptide of claim 1**, that can induce **expression** of the RB1 gene of the polypeptide or protein according to claim 1.

Group 14, claim(s) 14 and 15, drawn to a compound that was screened by the screening method according to claim 12, **using an antibody that immunologically recognizes the protein or polypeptide of claim 1** that can induce **transcription factor activity and expression** of the RB1 gene of the polypeptide or protein according to claim 1.

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Group 15, claim(s) 14 and 15, drawn to a compound that was screened by the screening method according to claim 12, **using an antibody that immunologically recognizes the protein or polypeptide of claim 1** that can induce **transcription factor activity** of the RB1 gene of the polypeptide or protein according to claim 1.

Group 16, claim(s) 14 and 15, drawn to a compound that was screened by the screening method according to claim 12, **using an antibody that immunologically recognizes the protein or polypeptide of claim 1** that can induce **expression** of the RB1 gene of the polypeptide or protein according to claim 1.

Group 17, claim(s) 16 and 17, drawn to a compound that interacts with the nucleic acid according to claim 4 to inhibit expression of the nucleic acid and a pharmaceutical composition for use in treatment of multidrug resistance that is resistance to treatment with anticancer agents, wherein the pharmaceutical composition comprises a compound that interacts with nucleic acid to inhibit expression of the nucleic acid.

Group 18, claim(s) 16 and 17, drawn to a compound that interacts with the nucleic acid according to claim 4 to enhance expression of the nucleic acid and a pharmaceutical composition for use in treatment of multidrug resistance that is resistance to treatment with anticancer agents, wherein the pharmaceutical composition comprises a compound that interacts with nucleic acid to enhance expression of the nucleic acid.

Claim 18 links inventions 19-23. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 18. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.

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In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP '

804.01.

Group 19, claim(s) 19, 20, and 22, drawn to a method of testing and diagnosing a disease related with expression or activity of the polypeptide or protein according to claim 1, wherein the method comprises a step of conducting analysis employing (a) a nucleic acid encoding the polypeptide or protein and/or (b) the polypeptide or protein, as a marker in a sample, wherein the method utilizes an antibody that immunologically recognizes the polypeptide, wherein the method combines assay of expression, increase, decrease, mutation, lack or insertion or the like of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene) or the gene product thereof (RB1 protein).

Group 20, claim(s) 19-22, drawn to a method of testing and diagnosing a disease related with expression or activity of the polypeptide or protein according to claim 1, wherein the method comprises a step of conducting analysis employing (a) a nucleic acid encoding the polypeptide or protein and/or (b) the polypeptide or protein, as a marker in a sample, which detects expression, mutation, lack or insertion or the like of all or a part of a gene encoding the polypeptide or protein through a step of amplifying a gene encoding the polypeptide or protein utilizing at least one of nucleic acid primers set forth in SEQ ID NOS: 5 to 132 in the sequence listing, which hybridize under stringent conditions with the nucleic acid, wherein the method combines assay of expression, increase, decrease, mutation, lack or insertion or the like of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene) or the gene product thereof (RB1 protein).

Group 21, claim(s) 19, 20, and 23, drawn to a method of testing and diagnosing a disease related with expression or activity of the polypeptide or protein according to claim 1, wherein the method comprises a step of conducting analysis employing (a) a nucleic acid encoding the polypeptide or protein and/or (b) the polypeptide or protein, as a marker in a sample, wherein the method utilizes an antibody that immunologically recognizes the polypeptide, wherein the method combines assay of expression, increase, decrease, mutation, lack or insertion or the like of all or a part of multidrug resistance gene (MDR1 gene) or the gene product thereof (MDR1 protein: P-glycoprotein).

Group 22, claim(s) 19-21, and 23, drawn to a method of testing and diagnosing a disease related with expression or activity of the polypeptide or protein according to claim 1, wherein the method comprises a step of conducting analysis employing (a) a nucleic acid encoding the polypeptide or protein and/or (b) the polypeptide or protein, as a marker in a sample, which detects expression, mutation, lack or insertion or the like of all or a part of a gene encoding the polypeptide or protein through a step of amplifying a gene encoding the polypeptide or protein utilizing at least one of nucleic acid primers set forth in SEQ ID NOS: 5 to 132 in the sequence listing, which hybridize under stringent conditions with the nucleic acid, wherein the method combines assay of expression, increase, decrease, mutation, lack or insertion or the like of all or a part of multidrug resistance gene (MDR1 gene) or the gene product thereof (MDR1 protein: P-glycoprotein).

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Group 23, claim(s) 19, 20, and 24, drawn to a method of testing and diagnosing a disease related with expression or activity of the polypeptide or protein according to claim 1, wherein the method comprises a step of conducting analysis employing (a) a nucleic acid encoding the polypeptide or protein and/or (b) the polypeptide or protein, as a marker in a sample, wherein the method combines assay of expression, increase, or decrease or the like of all or a part of the cell proliferation marker, Ki-67 protein.

Group 24, claim(s) 19-21 and 24, drawn to a method of testing and diagnosing a disease related with expression or activity of the polypeptide or protein according to claim 1, wherein the method comprises a step of conducting analysis employing (a) a nucleic acid encoding the polypeptide or protein and/or (b) the polypeptide or protein, as a marker in a sample, which detects expression, mutation, lack or insertion or the like of all or a part of a gene encoding the polypeptide or protein through a step of amplifying a gene encoding the polypeptide or protein utilizing at least one of nucleic acid primers set forth in SEQ ID NOS: 5 to 132 in the sequence listing, which hybridize under stringent conditions with the nucleic acid, wherein the method combines assay of expression, increase, or decrease or the like of all or a part of the cell proliferation marker, Ki-67 protein.

Group 25, claim(s) 25, drawn to a method a method that tests drug sensitivity of a cancer cell using the method according to claim 23.

Claim 26 is withdrawn because it is not possible to determine for which Group it is intended because it cannot be determined what the contents of the kit are, upon amendment it will be rejoined to the appropriate Group for examination.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be

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considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

The technical feature linking Groups 1-25 appears to be a protein or polypeptide which is present in nucleus of human or animal cell and which has a transcription factor function and/or a function that can induce expression of retinoblastoma gene (RB1 gene) or a gene product thereof. A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

The inventions listed as Groups 1-25 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups 1-25 appears to be a protein or polypeptide which is present in nucleus of human or animal cell and which has a transcription factor function and/or a function that can induce expression of retinoblastoma gene (RB1 gene) or a gene product thereof.

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However, Chano et al. (Oncogene, February 2002, 21:1295-1298, IDS) teach human RB1CC1 which is SEQ ID NO: 1 of the instant invention, see Abstract and Figure 1. Chano et al. teach that RB1CC1 enhances RB1 expression, see Abstract and Fig. 4.

Therefore, the technical feature linking the inventions of Groups 1-25 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

This application contains claims directed to the following patentably distinct species

Species Elections for Group 1

A. Claims 1 and 17 are generic to the following disclosed patentably distinct species of polypeptide:

1) SEQ ID NO: 1

2) SEQ ID NO: 2

Species Elections for Group 2

A. Claims 4-10 and 17 are generic to the following disclosed patentably distinct species of nucleic acid contemplated and claimed

1) SEQ ID NO: 3

2) SEQ ID NO: 4

B. Claim 10 and 17 are generic to the following disclosed patentably distinct species of nucleic acid primers:

1) SEQ ID NOs: 5 to 132

Applicants must elect one nucleic acid primer or a specific, defined combination of primers from ID NOs: 5 to 132.

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Species Elections for Group 3

A. Claims 11 and 17 are generic to the following disclosed patentably distinct species of polypeptide bound by the claimed antibody contemplated in the specification:

1) SEQ ID NO: 1

2) SEQ ID NO: 2

Species Elections for Groups 4-9

A. Claim 12 is generic to the following disclosed patentably distinct species of polypeptide contemplated in the specification:

1) SEQ ID NO: 1

2) SEQ ID NO: 2

Species Elections for Group 10

A. Claim 13 is generic to the following disclosed patentably distinct species of nucleic acid contemplated in the specification:

1) SEQ ID NO: 3

2) SEQ ID NO: 4

B. Claim 13 is generic to the following disclosed patentably distinct species of nucleic acid primers contemplated in the specification:

1) SEQ ID NOs: 5 to 132

Applicants must elect one nucleic acid primer or a specific, defined combination of primers from ID NOs: 5 to 132.

Species Elections for Groups 11-16

A. Claim 14 and 15 are generic to the following disclosed patentably distinct species of polypeptide contemplated in the specification:

- 1) SEQ ID NO: 1
- 2) SEQ ID NO: 2

Species Elections for Groups 17 and 18

A. Claims 16 and 17 are generic to the following disclosed patentably distinct species of nucleic acid contemplated in the specification:

- 1) SEQ ID NO: 3
- 2) SEQ ID NO: 4

Species Elections for Group 19

A. Claim 18 is generic to the following disclosed patentably distinct species of polypeptide contemplated in the specification:

- 1) SEQ ID NO: 1
- 2) SEQ ID NO: 2

B. Claim 18 is generic to the following disclosed patentably distinct species of assay:

- 1) of expression of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)
- 2) of increase of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)
- 3) of decrease of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)
- 4) of mutation of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)
- 5) of lack of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)

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- 6) of insertion of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)
- 7) of the like of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)
- 8) of expression of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)
- 9) of increase of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)
- 10) of decrease of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)
- 11) of mutation of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)
- 12) of lack of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)
- 13) of insertion of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)
- 14) of the like of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)

Applicants must elect one of a specific, defined combination of assays for examination.

C. Claim 18 is generic to the following disclosed patentably distinct species of marker contemplated in the specification:

- 1) SEQ ID NO: 1
- 2) SEQ ID NO: 2
- 3) SEQ ID NO: 3

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4) SEQ ID NO: 4

Species Elections for Group 20

A. Claim 18 is generic to the following disclosed patentably distinct species of polypeptide contemplated in the specification:

1) SEQ ID NO: 1

2) SEQ ID NO: 2

B. Claim 18 is generic to the following disclosed patentably distinct species of nucleic acid primers contemplated in the specification:

1) SEQ ID NOs: 5 to 132

Applicants must elect one nucleic acid primer or a specific, defined combination of primers from ID NOs: 5 to 132.

C. Claim 18 is generic to the following disclosed patentably distinct species of assay:

1) of expression of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)

2) of increase of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)

3) of decrease of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)

4) of mutation of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)

5) of lack of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)

6) of insertion of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)

7) of the like of all or a part of tumor-suppressor gene retinoblastoma gene (RB1 gene)

8) of expression of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)

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9) of increase of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)

10) of decrease of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)

11) of mutation of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)

12) of lack of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)

13) of insertion of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)

14) of the like of all or a part of tumor-suppressor gene retinoblastoma gene, gene product thereof (RB1 protein)

Applicants must elect one of a specific, defined combination of assays for examination.

D. Claim 18 is generic to the following disclosed patentably distinct species of marker contemplated in the specification:

1) SEQ ID NO: 1

2) SEQ ID NO: 2

3) SEQ ID NO: 3

4) SEQ ID NO: 4

Species Elections for Group 21

A. Claim 18 is generic to the following disclosed patentably distinct species of polypeptide contemplated in the specification:

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1) SEQ ID NO: 1

2) SEQ ID NO: 2

B. Claim 18 is generic to the following disclosed patentably distinct species of assay:

1) of expression of all or a part of MDR1 gene

2) of increase of all or a part of MDR1 gene

3) of decrease of all or a part of MDR1 gene

4) of mutation of all or a part MDR1 gene

5) of lack of all or a part of MDR1 gene

6) of insertion of all or a part of MDR1 gene

7) of the like of all or a part of MDR1 gene

8) of expression of all or a part of MDR1 protein

9) of increase of all or a part of MDR1 protein

10) of decrease of all or a part of MDR1 protein

11) of mutation of all or a part of MDR1 protein

12) of lack of all or a part of MDR1 protein

13) of insertion of all or a part of MDR1 protein

14) of the like of all or a part of MDR1 protein

Applicants must elect one of a specific, defined combination of assays for examination.

C. Claim 18 is generic to the following disclosed patentably distinct species of marker contemplated in the specification:

1) SEQ ID NO: 1

2) SEQ ID NO: 2

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3) SEQ ID NO: 3

4) SEQ ID NO: 4

Species Elections for Group 22

A. Claim 18 is generic to the following disclosed patentably distinct species of polypeptide contemplated in the specification:

1) SEQ ID NO: 1

2) SEQ ID NO: 2

B. Claim 18 is generic to the following disclosed patentably distinct species of nucleic acid primers contemplated in the specification:

1) SEQ ID NOs: 5 to 132

Applicants must elect one nucleic acid primer or a specific, defined combination of primers from ID NOs: 5 to 132.

C. Claim 18 is generic to the following disclosed patentably distinct species of assay:

1) of expression of all or a part of MDR1 gene

2) of increase of all or a part of MDR1 gene

3) of decrease of all or a part of MDR1 gene

4) of mutation of all or a part MDR1 gene

5) of lack of all or a part of MDR1 gene

6) of insertion of all or a part of MDR1 gene

7) of the like of all or a part of MDR1 gene

8) of expression of all or a part of MDR1 protein

9) of increase of all or a part of MDR1 protein

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- 10) of decrease of all or a part of MDR1 protein
- 11) of mutation of all or a part of MDR1 protein
- 12) of lack of all or a part of MDR1 protein
- 13) of insertion of all or a part of MDR1 protein
- 14) of the like of all or a part of MDR1 protein

Applicants must elect one of a specific, defined combination of assays for examination.

D. Claim 18 is generic to the following disclosed patentably distinct species of marker contemplated in the specification:

- 1) SEQ ID NO: 1
- 2) SEQ ID NO: 2
- 3) SEQ ID NO: 3
- 4) SEQ ID NO: 4

Species Elections for Group 23

A. Claim 18 is generic to the following disclosed patentably distinct species of polypeptide contemplated in the specification:

- 1) SEQ ID NO: 1
- 2) SEQ ID NO: 2

B. Claim 18 is generic to the following disclosed patentably distinct species of assay:

- 1) of expression of all or a part of Ki-67 gene
- 2) of increase of all or a part of Ki-67 gene
- 3) of decrease of all or a part of Ki-67 gene
- 4) of mutation of all or a part Ki-67 gene

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- 5) of lack of all or a part of Ki-67 gene
- 6) of insertion of all or a part of Ki-67 gene
- 7) of the like of all or a part Ki-67 gene
- 8) of expression of all or a part of Ki-67 protein
- 9) of increase of all or a part of Ki-67 protein
- 10) of decrease of all or a part of Ki-67 protein
- 11) of mutation of all or a part of Ki-67 protein
- 12) of lack of all or a part of Ki-67 protein
- 13) of insertion of all or a part of Ki-67 protein
- 14) of the like of all or a part of Ki-67 protein

Applicants must elect one of a specific, defined combination of assays for examination.

C. Claim 18 is generic to the following disclosed patentably distinct species of marker contemplated in the specification:

- 1) SEQ ID NO: 1
- 2) SEQ ID NO: 2
- 3) SEQ ID NO: 3
- 4) SEQ ID NO: 4

Species Elections for Group 24

A. Claim 18 is generic to the following disclosed patentably distinct species of polypeptide contemplated in the specification:

- 1) SEQ ID NO: 1
- 2) SEQ ID NO: 2

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B. Claim 18 is generic to the following disclosed patentably distinct species of nucleic acid primers contemplated in the specification:

1) SEQ ID NOs: 5 to 132

Applicants must elect one nucleic acid primer or a specific, defined combination of primers from ID NOs: 5 to 132.

C. Claim 18 is generic to the following disclosed patentably distinct species of assay:

1) of expression of all or a part of Ki-67 gene

2) of increase of all or a part of Ki-67 gene

3) of decrease of all or a part of Ki-67 gene

4) of mutation of all or a part Ki-67 gene

5) of lack of all or a part of Ki-67 gene

6) of insertion of all or a part of Ki-67 gene

7) of the like of all or a part Ki-67 gene

8) of expression of all or a part of Ki-67 protein

9) of increase of all or a part of Ki-67 protein

10) of decrease of all or a part of Ki-67 protein

11) of mutation of all or a part of Ki-67 protein

12) of lack of all or a part of Ki-67 protein

13) of insertion of all or a part of Ki-67 protein

14) of the like of all or a part of Ki-67 protein

Applicants must elect one of a specific, defined combination of assays for examination.

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D. Claim 18 is generic to the following disclosed patentably distinct species of marker contemplated in the specification:

- 1) SEQ ID NO: 1
- 2) SEQ ID NO: 2
- 3) SEQ ID NO: 3
- 4) SEQ ID NO: 4

Species Elections for Group 25

A. Claim 25 is generic to the following disclosed patentably distinct species of polypeptide contemplated in the specification:

- 1) SEQ ID NO: 1
- 2) SEQ ID NO: 2

B. Claim 25 is generic to the following disclosed patentably distinct species of assay:

- 1) of expression of all or a part of MDR1 gene
- 2) of increase of all or a part of MDR1 gene
- 3) of decrease of all or a part of MDR1 gene
- 4) of mutation of all or a part MDR1 gene
- 5) of lack of all or a part of MDR1 gene
- 6) of insertion of all or a part of MDR1 gene
- 7) of the like of all or a part of MDR1 gene
- 8) of expression of all or a part of MDR1 protein
- 9) of increase of all or a part of MDR1 protein
- 10) of decrease of all or a part of MDR1 protein

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11) of mutation of all or a part of MDR1 protein

12) of lack of all or a part of MDR1 protein

13) of insertion of all or a part of MDR1 protein

14) of the like of all or a part of MDR1 protein

Applicants must elect one of a specific, defined combination of assays for examination.

C. Claim 25 is generic to the following disclosed patentably distinct species of marker contemplated in the specification:

1) SEQ ID NO: 1

2) SEQ ID NO: 2

3) SEQ ID NO: 3

4) SEQ ID NO: 4

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 USC 103. Since the decisions in *In re Weber*, 198 USPQ 328 (CCPA 1978) and *In re Hass*, 198 USPQ 334 (CCPA 1978), it is proper for the Office to refuse to examine that which applicants regard as their invention, if the subject matter in a claim lacks unity of invention, see MPEP 803.02.

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Further some of the species are related as combination and subcombination. Species in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations is useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found

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allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Applicant is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

PJR

SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

